K082366
pg 1 of 3

SEP 2 6 2008

Special 510(k) Summary

Submitted By:	Hoana Medical Inc. 828 Fort Street Mall. Suite 620 Honolulu, HI 96813 Phone: (808) 523-1225 Fax: (808) 523-5480
Contact:	Nancy Gertlar Director of QA&RA Voice 808-523-1225 FAX 808-523-5480 Email ngertlar@Hoana.com
Date Summary Prepared:	August 15, 2008
Trade Name:	LifeBed Patient Vigilance System
Common/Classification Name:	Monitor, Cardiac 74DRT, 870.2300
Substantially Equivalent Devices:	LG1 Intelligent Medical Vigilance System (K052446)

Description of the LifeBed Patient Vigilance System:

The LifeBed Patient Vigilance System consists of two (2) main components: the bedside unit and the Passive Sensor Array™ (PSA™). The bedside unit houses the digital signal processing algorithms that calculate heart and respiratory rates and bed exit status (in-bed sensor) in real time and displays the data as part of the integrated graphical user interface. The bedside unit houses the alarm logic and interfaces to the existing nurse call system found in the hospital. The PSA is comprised of a mattress ticking ("coverlet" that slips over the entire mattress) that houses an array of sensors, which connect to the bedside unit via a cable with an integrated "quick disconnect" safety feature.

The LifeBed Patient Vigilance System's Passive Sensor Array (PSA) technology analyzes basic heart and respiratory physiology without direct patient contact, eliminating the use of electrodes, wires and leads. Hoana's PSA technology integrates proprietary signal processing algorithms with patented data collection devices that produce an electrical signal in response to physiological stimuli. The LifeBed Patient Vigilance System passively extracts patient measurements even through clothing, gowns or sheets.

Intended Use

The LifeBed Patient Vigilance System is intended to measure heart rate and respiratory rate in adult patients, in bed, in a general care hospital environment. The system will also monitor bed exit.

Principles of Operation

The LifeBed Patient Vigilance System operates in the following manner. The bed on a general care floor is fitted with the sensing array built into a sleep surface coverlet. Each bed is then fitted with a normal sheet and bedding above the coverlet.

The device measures heart rate and respiration and monitors those against a preset limit. If the bedside unit senses the heart rate or respiration rate is outside the desired limits for a period of time, it will signal the nurse with an alarm indicator using the standard nurse call system and the clinician will respond. If the patient has been evaluated as a risk to fall, the bed exit alarm can also be enabled. When the unit senses the patient is attempting to get out of bed, it will use the nurse call system to signal the nurse.

The system will trend and display graphics of heart rate and respiration rate and wave form graphic for respiration in 10 minute, 2, 4, 8, and 12 hour views of the data.

Electrical, Mechanical and EMC Testing

Electrical, Mechanical and EMC Testing per IEC 60601-1-2 was performed and the LifeBed Patient Vigilance System passed all tests.

Biocompatibility Testing

Biocompatibility was conducted according to the requirements of ISO 10993, *Biological Evaluation of Medical Devices, Table 1 – Initial Evaluation Tests for Consideration* for a surface device in contact with skin for less than 24 hrs. All test article materials passed.

Conclusion

This Special 510(k) submission covers only the change in the Graphical User Interface (GUI). This change meets the criteria for Special 510(k) under the New 510(k) Paradigm, which states that if the modification does not affect the intended use of the device or alter the fundamental scientific technology of the device, then summary information that results from the design control process can serve as the basis for clearing the application.

There is no change in the indications for use.

There are no changes to labeling that affects the intended use.

There is no change in the fundamental scientific technology of the device.

There are no changes in materials.

Device modifications that should be appropriate for review as a Special 510(k) include "ergonomics of the patient-user interface." This change in GUI is the only change to the original submission covered by this Special 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

Hoana Medical, Inc.
c/o Ms. Nancy Gertlar
Director of Regulatory Affairs and Quality Assurance
828 Fort Street Mall Suite 620
Honolulu, HI 96825

Re: K082366
Trade/Device Name: LifeBed Patient Vigilance System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: DRT
Dated: September 6, 2008
Received: September 10, 2008

Dear Ms. Gertlar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or

any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082366

Device Name: **LIFEBED PATIENT VIGILANCE SYSTEM**

Indications for Use:

The LifeBed Patient Vigilance System is intended to measure heart rate and respiratory rate in adult patients, in bed, in a general care hospital environment. The system will also monitor bed exit.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082366

(Posted November 13, 2003)